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MEMORANDUM

This memo will answer some of the basic and commonly asked questions regarding the installation and operation of a diagnostic Bone Mineral Densitometer to detect osteoporosis.

1. As a manufacturer and installer of equipment, are you required to register?

Yes. There is no cost for this process and appropriate forms are available. (R12-1-1-203)

2. Sales Representatives will be in possession of the x-ray machine in the state for demonstration purposes in the Doctor's Office. What are the requirements?

- A. The Agency must be notified at least three days in advance that you are bringing a x-ray machine into the state for temporary use.
- B. Sales Representatives may demonstrate the unit to physicians, however, only the physician or an MRTBE (Medical Radiologic Technologists Board of Examiners) Technologist is allowed to expose a human.
- C. If the machine is used on an extremity, a certified (MRTBE) practical technologist in radiology (limited to chest and extremities) may perform the examination.
- D. If the machine is used on the foot/ankle area, a certified (MRTBE) practical technologist in podiatry (limited to the foot and ankle) may perform the examination.

3. Is there a waiting period following registration as an installer before a machine demonstration can take place?

Not typically.

4. Are we required to notify the Agency prior to each demonstration?

No. There are rules, which must be followed, however, for using the equipment properly. An example of an activity that might not be permitted could be demonstration of the x-ray equipment at a convention, a "state health fair", a mall area or other public areas such as waiting rooms. Studies performed on patients require a walled off area out of public view, such as a Doctor's Exam Room or other isolated area where it would be highly unlikely that anyone in the area would perceive that they received scatter radiation from the procedure. ((R12-1-604 (A) (2), R12-1-607 (D) (2))

5. Is the customer (typically a physician) required to register their machine with our Agency?

Yes, if they become the owner or possessor of a machine. The manufacturer notifies the Agency of the purchase or installation of the machine. The owner or possessor is then mailed the appropriate application forms to fill out and return to the Agency. After the application is reviewed and approved, a Notice of Registration is issued. (R12-1-202)

6. What are the qualifications required to operate radiation emitting devices on humans within Arizona?

The technologist must be certified by MRTBE, or be a licensed practitioner (MD, DO, Dentist, Chiropractor, Naturopath or Podiatrist) and exempt from the rules. (R12-1-603 (B))

7. What restrictions with respect to the operation of radiation emitting devices should you be aware of?

Because the radiation emitted from a x-ray bone mineral densitometer is generally considered to be less when compared to a normal radiography unit, spatial and protective devices are somewhat less restrictive than would otherwise be required. (R12-1-407)

8. Are manufacturers required to inform the Agency of installations?

Yes, the FDA 2579 REPORT OF ASSEMBLY, may be used or another form letter. We have no specific format or form requirement for this purpose. Indication of the Machine Model Number, Serial Numbers, Tube Housing Model & Serial numbers; and maximum kVp and mA are required. (R12-1-206 (A))

9. Given that the intended x-ray exposure to the patient is so low, and that the unintended leakage is even lower, is it possible to obtain a deviation or waiver for one or more requirements?

Yes, it is always possible to request a waiver of a specific rule. However, the granting of a rule waiver is very rare.

In addition to the above information, screening or self-referral for osteoporosis x-ray examinations is not permitted in Arizona under current law, unless the physician performs the actual examination. This means that there must be a patient/physician relationship prior to the x-ray exam and that the patient must present a prescription written by an Arizona licensed physician to the x-ray technologist prior to the exam, for each exam.

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